



RECEIVED  
MAY 14 2003  
TECH CENTER  
PATENT

Atty. Dkt. No. ABI1550-1  
(071243-1404)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Soon-Shiong and Desai  
Title: LONG TERM ADMINISTRATION  
OF PHARMACOLOGICALLY  
ACTIVE AGENTS  
Appl. No.: 09/937,840  
Filing Date: 09/26/2001  
Examiner: Unknown  
Art Unit: 1614

<b>CERTIFICATE OF MAILING</b> I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.  <u>Stephen E. Reiter, Reg. No 31,192</u> (Printed Name)  <u>Stephen E. Reiter</u> (Signature)  <u>5/9/03</u> (Date of Deposit)
--

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**IDS TRANSMITTAL**

Sir:

Transmitted herewith for the above-identified application please find:

- (1) Information Disclosure Statement.
- (2) Completed Form PTO/SB/08.
- (3) Copies of the cited references
- (4) Postcard.

In re Application of:  
Soon-Shiong and Desai  
Application No.: 09/937,840  
Page 2

PATENT  
Atty. Dkt. No.: ABI1550-1  
(071243-1404)

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date 5/9/03

FOLEY & LARDNER  
Customer Number: 30542



30542

PATENT TRADEMARK OFFICE

Telephone: (858) 847-6711  
Facsimile: (858) 792-6773

By Stephen E. Reiter

Stephen E. Reiter  
Attorney for Applicant  
Registration No. 31,192



Atty. Dkt. No. 09/937,840-1

(071243-0404)

RECEIVED  
MAY 14 2003  
TECH CENTER 1600/2900

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Soon-Shiong and Desai  
Title: LONG TERM ADMINISTRATION  
OF PHARMACOLOGICALLY  
ACTIVE AGENTS  
Appl. No.: 09/937,840  
Filing Date: 09/26/2001  
Examiner: Unknown  
Art Unit: 1614

<p><b>CERTIFICATE OF MAILING</b></p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450, on the date below.</p> <p><u>Stephen E. Reiter, Reg. No. 31,192</u> (Printed Name)</p> <p><u>SEP E. L.</u> (Signature)</p> <p><u>5/9/03</u> (Date of Deposit)</p>
---

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Some of the documents were cited in the International Search Report for corresponding international application PCT/US00/10849. Some of the documents were cited in the Supplementary European Search Report for corresponding European Patent Application No. EP 00 92 8296. A copy of both of the Reports is included.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed

herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

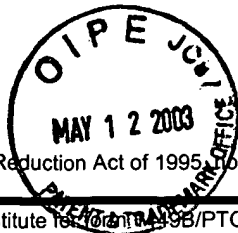
Respectfully submitted,

Date 5/9/03

By SEP EL

FOLEY & LARDNER  
P.O. Box 80278  
San Diego, California 92138-0278  
Telephone: (858) 847-6711  
Facsimile: (858) 792-6773

Stephen E. Reiter  
Attorney for Applicant  
Registration No. 31,192



MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for Form PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 4

**Complete if Known**

Application Number	09/937,840
Filing Date	09/26/2001
First Named Inventor	Patrick Soon-Shiong
Group Art Unit	1614
Examiner Name	Unknown
Attorney Docket Number	ABI1550-1 (071243-1404)

**RECEIVE****MAY 14 2003  
TECH CENTER 1600/2****U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	5,041,292		Feijen	Aug. 20, 1991	
	A2	5,631,018		Zalipsky et al.	May 20, 1997	
	A3	5,714,166		Tomalia et al.	Feb. 3, 1998	
	A4	5,723,147		Kim et al.	Mar. 3, 1998	
	A5	5,756,537		Gill	May 26, 1998	
	A6	5,766,627		Sankaram et al.	Jun. 16, 1998	
	A7	5,772,992		Bauer et al.	Jun. 30, 1998	
	A8	5,789,248		Fodstad et al.	Aug. 4, 1998	
	A9	6,066,668		Hausheer et al.	May 23, 2000	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A10	WO	94/06422		Government of the United States as represented by The Secretary, Department of Health and Human Services	March 31, 1994		

**NON PATENT LITERATURE DOCUMENTS**

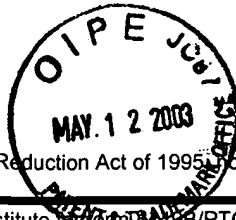
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A11	International Search Report for PCT Application No. PCT/US00/10849	
	A12	Supplementary European Search Report for European Patent Application No. EP 00 92 8296.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.



MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for PTO		<b>Complete if Known</b>			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Application Number</b>	09/937,840		
		<b>Filing Date</b>	09/26/2001		
		<b>First Named Inventor</b>	Patrick Soon-Shiong		
		<b>Group Art Unit</b>	1614		
		<b>Examiner Name</b>	Unknown		
<b>Sheet</b>	2	<b>of</b>	4	<b>Attorney Docket Number</b>	ABI1550-1 (071243-1404)

RECEIVED  
MAY 14 2003  
TECH CENTER 1600

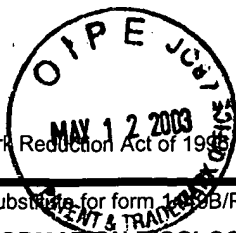
NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A13	Arbuck et al., "Clinical Development of Taxol." Journal of the National Cancer Institute Monographs No. 15, p. 11-24, 1993.	
	A14	Dorr, "Pharmacology of the Taxanes." Pharmacotherapy, 17:965-1045, 1997.	
	A15	Eisenhauer et al., "European-Canadian randomized trial of Paclitaxel in relapsed ovarian cancer: high-dose versus low-dose and long versus short infusion." Journal of Clinical Oncology, 12:2654-2666, 1994.	
	A16	Fennelly et al., "Phase I and pharmacologic study of Paclitaxel administered weekly in patients with relapsed ovarian cancer." Journal of Clinical Oncology, 15:187-192, 1997.	
	A17	Fletcher et al., "Antinociceptive effect of bupivacaine encapsulated in Poly(D,L)-Lactide-Co-Glycolide microspheres in the acute inflammatory pain model of carrageenin-injected rats." Anesth. Analg., 84:90-94, 1997.	
	A18	Gianni et al., "Nonlinear pharmacokinetics and metabolism of Paclitaxel and its pharmacokinetic/pharmacodynamic relationships in humans." Journal of Clinical Oncology, 13:180-190, 1995.	
	A19	Greco et al., "One-hour Paclitaxel infusions: review of safety and efficacy." The Cancer Journal, 5: 179-191, 1999.	
	A20	Holmes et al., "Final Results: Randomized phase III trial of Paclitaxel by 3-hour versus 96-hour infusion in patients (PT) with MET breast cancer. The long and short of it." Meeting Abstract. Proceedings of the American Society of Clinical Oncology, 16:110a, 1998.	
	A21	Holmes et al., "Phase III trial of pactitaxel (P) administered over 3- or 96-hr for metastatic breast cancer (MBC)." Meeting Abstract. Proceedings of the American Society of Clinical Oncology, 15:106a, 1996.	
	A22	Hainsworth et al., "Carcinoma of unknown primary site: Treatment with 1-hour Paclitaxel, Carboplatin, and extended-schedule Etoposide." Journal of Clinical Oncology, 15:2385-2393, 1997.	

<b>Examiner Signature</b>		<b>Date Considered</b>	
---------------------------	--	------------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.



MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1-800/PTO  
**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 4

**Complete if Known**

Application Number	09/937,840
Filing Date	09/26/2001
First Named Inventor	Patrick Soon-Shiong
Group Art Unit	1614
Examiner Name	Unknown
Attorney Docket Number	ABI1550-1 (071243-1404)

**RECEIVED****MAY 14 2003**  
**TECH CENTER**  
**600/290****NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A23	Hainsworth et al., "Paclitaxel administered by a 1-hour infusion: A Phase 1-11 trial comparing two schedules." The Cancer Journal from Scientific American, 1:281-287, 1995.	
	A24	Hainsworth et al., "Paclitaxel by 1-hour infusion: An Active drug in metastatic non-small-cell lung cancer." Journal of Clinical Oncology, 13:1609-1614, 1995.	
	A25	Hainsworth et al., "Paclitaxel, carboplatin, and extended-schedule etoposide in the treatment of small-cell lung cancer: comparison of sequential phase II trials using different dose-intensities." Journal of Clinical Oncology, 15:3464-3470, 1997.	
	A26	Huizing et al., "Pharmacokinetics of Paclitaxel and metabolites in a randomized comparative study in platinum-pretreated ovarian cancer patients." Journal of Clinical Oncology, 11:2127-2135, 1993.	
	A27	Kearns et al., "Paclitaxel pharmacokinetics and pharmacodynamics." Seminars in Oncology, 22:16-23, 1995.	
	A28	Klaassen et al., "Phase I study with a weekly 1 h infusion of paclitaxel in heavily pretreated patients with metastatic breast and ovarian cancer." European Journal of cancer, 32A: 547-549, 1996.	
	A29	Langer et al., "Paclitaxel (P) by 1 or 24 hour (HR) infusion combined with carboplatin © in advanced non-small cell lung carcinoma (NSCLC): a comparative analysis." Meeting abstract. Proceedings of the American Society of Clinical Oncology, 16:45a, 1997.	
	A30	Lopes et al., "Cell kill kinetics and cell cycle effects of taxol on human and hamster ovarian cell lines." Cancer Chemotherapy and Pharmacology, 32:235-242, 1993.	

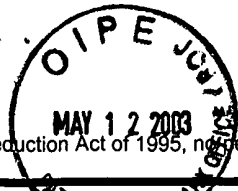
Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.





Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for Form 1449B, PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	09/937,840
		Filing Date	09/26/2001
		First Named Inventor	Patrick Soon-Shiong
		Group Art Unit	1614
		Examiner Name	Unknown
Sheet	4	of	4
		Attorney Docket Number	ABI1550-1 (071243-1404)

RECEIVED  
MAY 4 2002  
TECH CENTER 1600

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A31	Obtsu et al., "Clinical pharmacokinetics and pharmacodynamics of paclitaxel: A 3-hour infusion versus a 24-hour infusion." Clinical Cancer Research, 1:599-606, 1995.	
	A32	Onetto et al., "Overview of taxol safety." Journal of the National Cancer Institute, Monographs No. 15, p. 131-139, 1993.	
	A33	Seidman et al., "One-hour paclitaxel via weekly infusion: Dose-density with enhanced therapeutic index." Oncology, Vol. 12, No. 1, Supplement No. 1, p. 19-22, 1998.	
	A34	Sonnichsen et al., "Saturable pharmacokinetics and paclitaxel pharmacodynamics in children with solid tumors." Journal of Clinical Oncology, 12: 532-538, 1994.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.